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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,431	07/22/2004	Curtis C. Harris	4239-64141-02	3960
36218	7590	10/02/2006	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988			HALVORSON, MARK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/502,431	HARRIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)                      |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application            |
| Paper No(s)/Mail Date _____  | 6) <input checked="" type="checkbox"/> Other: <u>sequence search results</u> |

### **DETAILED ACTION**

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claim 27 is missing. Misnumbered claims 28-43 have been renumbered 27-42.

Claims 1-42 are pending.

### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 1-2, drawn to a tumor suppressor protein.

Group 2, claims 3-9, 11-19 and 40-42 drawn to an oligonucleotide.

Group 3, claim 10, drawn to a transgenic animal.

Group 4, claims 20 and 21, drawn to a method of inhibiting cellular proliferation comprising transfecting a cell.

Group 5, claims 22 and 23, drawn to a method of inhibiting cellular proliferation comprising contacting a cell with the protein.

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Group 6, claim 24 and 25 drawn to a method of enhancing cellular proliferation comprising transfecting a cell.

Group 7, claim 26, drawn to a specific binding agent.

Group 8, claim 27, drawn to a method of screening for an agent that modulates tumor suppressor activity.

Group 9, claim 28, drawn to a method of detecting a tumor suppressor protein in a biological sample.

Claim 29-34 link(s) inventions 10 and 11. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 30-35. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 10, claim 35, drawn to a method of diagnosing the presence of a tumor comprising amplifying the nucleotide of SEQ ID NO:1.

Group 11, claim 36, drawn to a method of diagnosing a tumor in a subject comprising identifying a mutation.

Group 12, claim 37, drawn to a method of treating a neoplasm.

Group 13, claim 38, drawn to a kit comprising an antibody specific for p28ING5 protein.

Group 14, claim 39, drawn to a kit comprising an amplification primer that specifically amplifies the nucleic acid that encodes the p28ING5 protein.

3. A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding, special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c), 37 C.F.R. 1.475(d)

The invention listed as Groups 1-14 do not relate to a single inventive concept under PCT Rule 1.31 because, under PCT 13.2 they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking Groups 1-14 appears to be that they all relate to a tumor suppressor protein, p28ING5, comprising amino acid residues 1-13 of SEQ ID NO:2.

However, Marcu (U.S. Patent No:6, 066, 474, issued May 23, 2000) describes an IKK binding protein comprising amino acid residues 1-14 of SEQ ID NO:1 of the present application (see sequence search). Thus, Marcu's protein reads on the instant applicant's p28ING5 protein comprising amino acids 1-14.

Thus, the different groups in the present application do not contain a single inventive concept and can be separated accordingly.

#### **SPECIES ELECTION**

4. This application contains claims directed to the following patentably distinct species of the claimed invention.

(i). **Groups 9 and 10** are subject to election of at least one of the disclosed species.

Claim 30 is generic to a plurality of disclosed patentably distinct tumors, the tumors being breast tumor, a lung tumor, a colon tumor, a pancreatic tumor, a liver tumor, a brain tumor, a skin tumor, a prostate tumor, a testicular tumor, an ovarian tumor, a stomach tumor, or a tumor of the blood.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected

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invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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571-272-6539



MISOOK YU  
PRIMARY EXAMINER